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Original Article

Assessing Safety and Gender-based Variations in Cardiac Pacemakers and Related Devices: Results from a Prospective Cohort Study

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Abstract

Background and objectives: Cardiac pacemaker implantation is a primary therapy for various arrhythmic disorders; however, safety concerns persist in India. This study aimed to evaluate two-year safety outcomes of cardiac pacemakers, implantable cardioverter-defibrillators, and cardiac resynchronization therapy devices in a tertiary care setting.

Methods: In this prospective cohort study, data collection was conducted over a one-year enrolment period (February 2023 to January 2024), encompassing patient demographics, pacemaker implantation details, indications, and comorbidities. Patients were prospectively followed for a total of two years from enrolment—during the data collection period and for an additional year, to record device-associated adverse events. Ethical approval was obtained (IECJNMC/1662), and data were analyzed using SPSS.

Results: Among 183 patients, 95% received cardiac pacemakers, 3% cardiac resynchronization therapy devices, and 2% implantable cardioverter-defibrillators. The data comprised 58% males (mean age, 63 years). The adverse event rate was 5.5% (10/183), distributed as 3.8% device infection, 1.09% lead dislodgement, and 0.54% generator dysfunction, with no statistical difference between males and females ($P > 0.05$). Different age groups, various indications, and several comorbidities showed no significant disparities ($P > 0.05$) between males and females. The Cox model showed no significant effect of several predictors on the occurrence of adverse events ($P > 0.05$). The Kaplan–Meier survival curve revealed a higher incidence of adverse events in the first six months, followed by stabilization. Adverse events were appropriately documented and reported to the Indian Pharmacopoeia Commission.

Conclusions: The observed adverse event rate of 5.5% supports previous Indian and international data; however, the smaller sample size and short follow-up duration warrant further investigation for more specific outcomes.

Keywords: Adverse event; Medical device; Cardiac pacemaker; Cardiac implantable electronic device; CIED; Permanent pacemaker implantation; PPI; Implantable cardioverter defibrillator; ICD; Cardiac resynchronization therapy; CRT; Observational study.

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Introduction

Cardiac arrhythmias, characterized by irregular heartbeats, pose a significant threat to human health, often necessitating interventions such as the insertion of pacemakers and other cardiac implantable electronic devices (CIEDs). The increasing application of CIEDs, including simpler cardiac pacemakers (CPs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) with a pacemaker or defibrillator, reflects advancements in medical technology and the growing need for effective treatment options in managing arrhythmias.[1,2] However, the safety profiles of these devices are not well documented or reported in the Indian context.[3,4]

Older individuals are significantly more likely to receive CIEDs, with approximately 70–80% of devices being implanted in those aged 65 and above.[5–7] There has been a 14% increase in the use of advanced pacing systems,[8,9] indicating a growing reliance on these devices, particularly in cases where pharmacological management of cardiac arrhythmias is limited. Pacemaker implantation demonstrates a high success rate with considerable accuracy and safety; however, there remain several post-procedural risks associated with these implants, such as device infections (e.g., pocket infections, infective endocarditis), pacing lead complications (e.g., lead fracture and lead dislodgement), generator dysfunction, etc.[10,11]

The existing literature reflects the evolving landscape of cardiac disease management with such devices,[12] highlighting both the complexities and advancements in managing cardiac conduction abnormalities.[13,14]A gap in reporting, or the under-reporting, of post-procedural adverse events associated with such medical devices may therefore lead to underestimation of the risks associated with these life-saving technologies.[15] Moreover, the lack of data on adverse event reporting may hinder the development of safety protocols and limit our understanding of the potential long-term consequences of such medical devices.[16]

By collecting detailed data on patient demographics, procedural characteristics, devices, and adverse events, this study aimed to provide insights into the real-world safety profile of these cardiac implants. In India, this study is the first of its kind to record and simultaneously report post-procedural complications (i.e., adverse events associated with CIEDs) to the Indian Pharmacopoeia Commission (IPC) under the Materiovigilance Programme of India (MvPI, a national materiovigilance initiative by the Government of India to monitor and regulate medical device–associated activities). Additionally, we established a gender-based examination comparing various CIED-associated parameters. This research will not only lead researchers to conduct further comparable single-centre and single-arm prospective observational studies but also produce real-time safety data on CIED implantation.

Materials and methods

By reviewing various relevant investigations, we recorded the patient characteristics and followed methodologies within the scope of our study. These optimized characteristics and methods are discussed below.

Study design

In this prospective cohort, we included all patients receiving a CIED for the first time between February 2023 and January 2024. Ethical approval for this study was obtained from the Institutional Ethics Committee of J.N. Medical College & Hospital (JNMCH, Aligarh Muslim University, Aligarh, India) under approval number IECJNMC/1662. Permission to access and analyze the data collected from the Catheterization Laboratory was granted by the Department of Cardiology (JNMCH). Individual informed consent was obtained from each patient prior to his/her participation in this study. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki (revised 2024). The study followed MvPI guidelines for medical device safety and was informed by relevant previous research.[17–22] It was conducted in line with the Declaration of Helsinki and approved by the Institutional Ethics Committee (IECJNMC/1662) of JNMCH, AMU.

Study outcomes

The primary outcome of the study was to analyze the overall adverse event rate with survival free from any adverse events. The secondary outcome was to assess the impact of various baseline predictors on the occurrence of adverse events at a two-year follow-up. The tertiary outcome was to identify differences between males and females for variables such as adverse events, indications, comorbidities, age, and treatments.

Data collection and follow-up

Data collection was performed by reviewing the medical records of 219 patients for: (i) *patient demographics*; (ii) *device implantation details*; and (iii) *details of adverse events*. Out of 219 patients, 36 were excluded from the study according to the selection criteria, and 183 patients were included in the data collection (Fig. 1). The collected variables were followed up in parallel with the data collection period (i.e., one year) and further for one additional year (total of two years) to observe any device-related adverse events. In addition, follow-up was conducted according to clinical intervals; patients were advised to visit the hospital at intervals of one, three, six, and twelve months. Patients who did not visit the hospital were contacted telephonically at the completion of the study tenure to record possible adverse outcomes (if any). Patients who could not be reached during telephonic follow-up were marked as alive and censored in the statistical analysis.

Selection criteria and indications for pacemaker implantation

We summarized the indications leading to pacemaker or defibrillator implantation as symptomatic observations supported by electrocardiographic (ECG) analysis. The included ECG patterns were AV block (AVB 2:1), complete heart block (CHB), sick sinus syndrome (SSS), left bundle branch block with severe systemic left ventricular dysfunction, and temporary pacemaker implantation. Symptoms included brief loss of consciousness, dizziness with or without syncope, syncopal or non-syncopal bradycardia, and clinical dyspnea. Patients with comorbidities such as hypertension (HTN), type2 diabetes mellitus (T2DM), dilated cardiomyopathy (DCM), coronary artery disease (CAD), acute myocardial infarction (AMI), transcatheter aortic valve replacement (TAVR), and HTN + T2DM were considered, regardless of gender. Patients were excluded if a heart transplant was planned within 12 months, if they had a scheduled lead extraction (due to infection or other causes), or if they experienced stroke, collapse, or death during the procedure (see Fig. 1).

Adverse event detection

To identify device-associated adverse events, a comprehensive range of investigations was performed based on patient need and suitability, including clinically suspected indications (such as syncope, chest pain, fever, dyspnea, etc.), ECG, computed tomography scan, echocardiogram, bacterial culture and sensitivity testing, complete blood count, and biochemical estimations (cardiac disease biomarkers such as troponin I, brain natriuretic peptide, creatine kinase-MB, and glucose).

Adverse event assessment

Following detection of an adverse event, each patient was critically and comprehensively assessed using a standardized methodology aligned with MvPI guidelines. The assessment process involved three key steps[17]: (a) *baseline study*, to understand the patient's condition and the implanted device malfunction; (b) *causality assessment,* to establish a relationship between the time of device implantation and event occurrence using a systematic approach; and (c) *root cause identification,* to determine the underlying cause

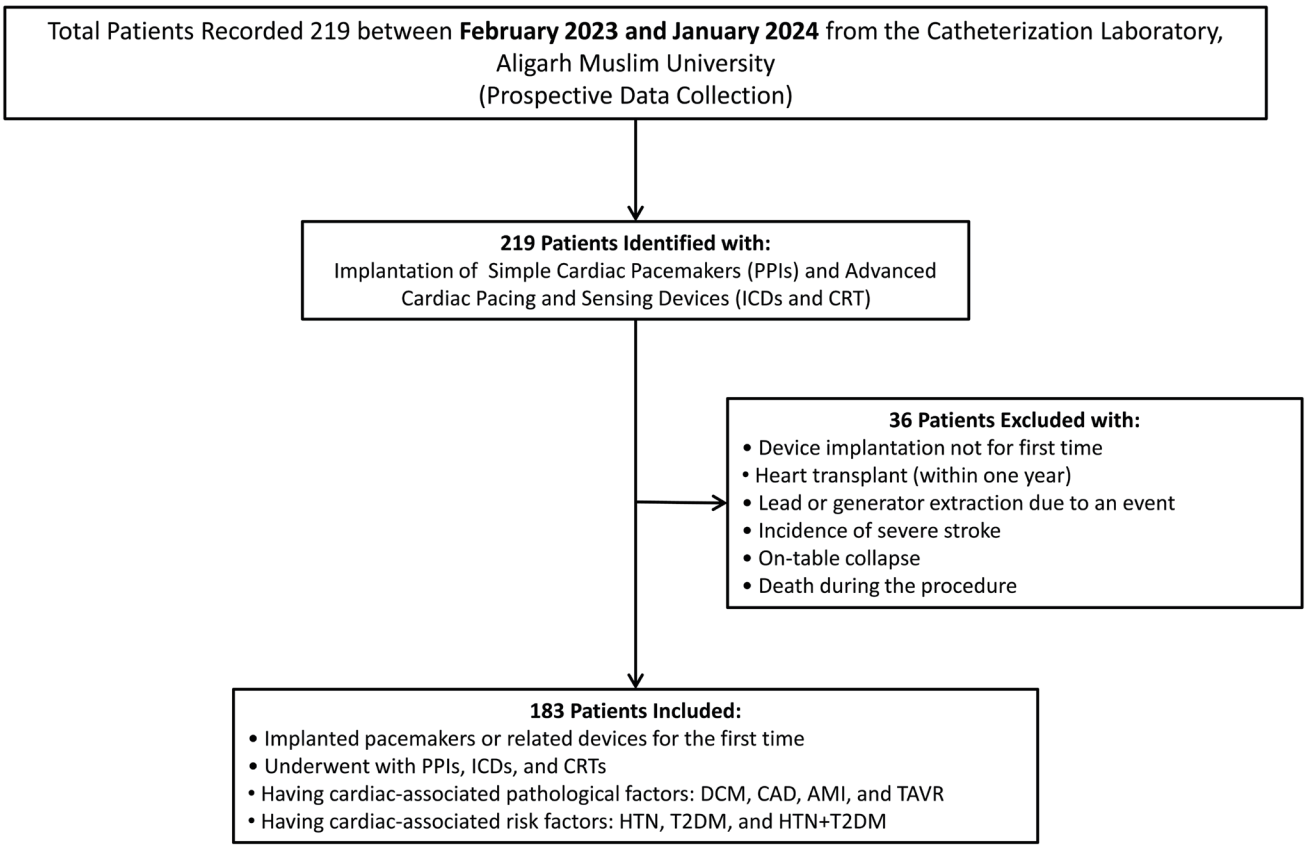


Fig. 1. A schematic STROBE diagram of patient inclusion and exclusion methodology. The flowchart outlines the methodological process used to screen the study population in accordance with STROBE guidelines. It presents the applied inclusion and exclusion criteria, along with the resulting final sample size, in a stepwise schematic representation. AMI, acute myocardial infarction; CAD, coronary artery disease; CRT, cardiac resynchronization therapy; DCM, dilated cardiomyopathy; HTN, hypertension; ICD, implantable cardioverter defibrillator; PPI/CP, permanent pacemaker implantation/cardiac pacemaker; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; T2DM, type2 diabetes mellitus; TAVR, transcatheter aortic valve replacement.

of the adverse event based on MvPI criteria for the device–event relationship: Not Related < Possible < Probable < Related.

Adverse event reporting

The adverse drug reaction monitoring system (ADRMS) software was used to report all recorded and clinically confirmed post-procedural adverse events of CIEDs as Individual Case Safety Reports (ICSRs). All recorded and documented ICSRs were reported within 15 calendar days following the occurrence of an event. ADRMS is an Indian government online tool used to report adverse drug reactions or medical device adverse events. Each reported adverse event was reviewed and approved by the Causality Assessment Committee of JNMC, AMU.

Statistical analysis

SPSS version 25.0 was used to analyze and predict the outcomes of all proposed variables. Continuous variables were presented as means ± standard deviation and were examined using the Mann–Whitney U test or independent Student's t test, as appropriate. Categorical variables were presented as proportions, frequencies, or percentages and were examined using the chi-square test of independence or Fisher's exact test, as appropriate. For freedom from any adverse events, the time from pacemaker implantation to the occurrence of an adverse event was considered. Survival probabilities in terms of freedom from adverse events were estimated using the Kaplan–Meier model. To assess associations between baseline predictors and the incidence of adverse events at a two-year follow-up, the Cox proportional hazards regression model with a 95% confidence interval was also performed. A *P*-value of less than 0.05 ($P < 0.05$) was considered statistically significant for all analyses.

Results

Study population

Patients who underwent cardiac implant procedures with CP, ICD, and CRT were recruited for the study. During the study period, a total of 183 patients were found eligible for inclusion in the study, while 36 patients were excluded. These patients had cardiac-associated pathological factors such as TAVR, DCM, CAD, and AMI, and cardiac-associated risk factors such as HTN, T2DM, and HTN + T2DM.

Patient characteristics

The baseline characteristics of the study population encompassed age, gender, indications, treatments, surgical procedure setup, and comorbidities. The cohort comprised 58% males (107/183) and

Table 1. Patients' demographic and clinical characteristics of those implanted with cardiac implantable electronic devices from February 2023 to January 2024

Patients characteristics	Numbers (%)
Number of patients	n = 183
Age (Yrs)	
Range	10 – 90
Mean ± standard deviation	63 ± 13.95
95% confidence interval (CI)	61–65
Gender	
Male, n (%) [95% CI]	107 (58%) [58–67]
Device implantation (or treatments)	
Cardiac pacemakers (CPs)	n = 173 (95%)
Cardiac resynchronization therapy (CRT)	n = 006 (3%)
Implantable cardioverter defibrillator (ICD)	n = 004 (2%)
Co-morbidities	
Systemic hypertension (HTN)	n = 24 (13%)
Type-II diabetes mellitus (T2DM)	n = 20 (11%)
Dilated cardiomyopathy (DCM)	n = 13 (7%)
Coronary artery disease (CAD)	n = 12 (7%)
Acute myocardial infarction (AMI)	n = 6 (3%)
Transcatheter aortic valve replacement (TAVR)	n = 5 (3%)
HTN plus T2DM	n = 3 (2%)
Major indications	
Complete heart block (CHB)	n = 92 (50%)
Atrioventricular block (2:1, AVB)	n = 45 (25%)
Sick-sinus syndrome (SSS)	n = 35 (19%)
Surgeries following temporary pacemaker implantation (TPI)	
TPI	n = 8 (4%)
Surgical procedures	Parameters
Pocket type	Pre-pectoral: n = 181 (99%)
	Sub-pectoral: n = 2 (1%)
Access site	Axillary vein: n = 176 (96%)
	Cephallic vein: n = 7 (4%)
Pacing lead	Bipolar: n = 181 (99%)
	Unipolar: n = 2 (1%)
Pacing lead fixation	Passive: n = 103 (56%)
	Active: n = 80 (44%)
Pacing mode	Single-chamber: n = 112 (61%)
	Dual-chamber: n = 71 (39%)

42% females (76/183), with a mean age of 63 years (range: 10–90 years) (Table 1). The primary objective was to investigate the association between gender and variables, including age, indications, comorbidities, and treatments, specifically focusing on patients undergoing CIED implantation for the first time.

The analysis of age distribution in relation to first-time pacemaker implantation between male and female patients demonstrated no statistically significant difference (P = 0.67) (Fig. 2). Three primary indications for pacemaker implantation were identified: CHB (50%), AVB (25%), and SSS (19%), indicating the

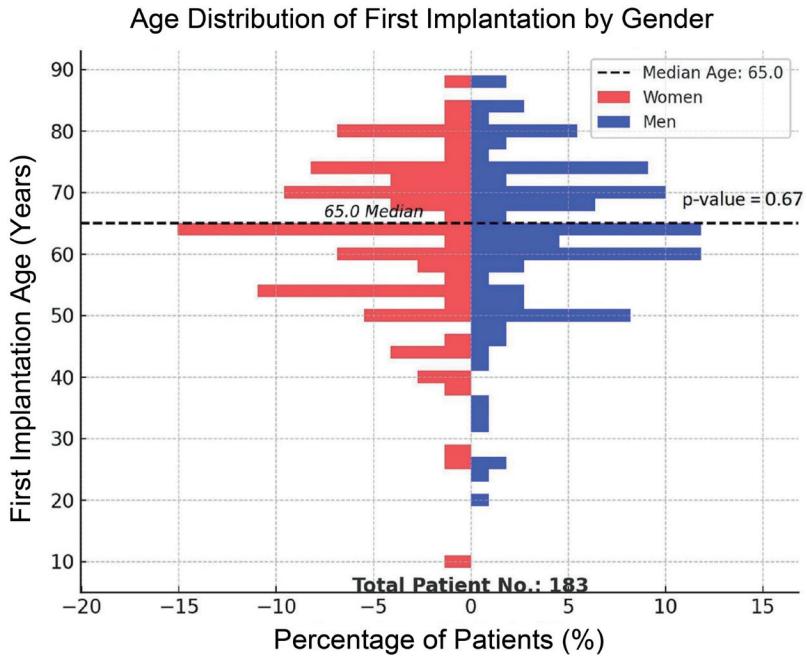


Fig. 2. A representation of the age distribution by gender. This estimation shows no significant difference between males and females who received CIEDs for the first time, with a median age of 65 years. For receiving a pacemaker for the first time, males and females were observed to be equally opportunistic. Therefore, the gender variable alone does not affect the rate of pacemaker implantation. CIED, cardiac implantable electronic devices.

highest pacemaker implantation due to CHB. Additionally, 4.4% of patients underwent permanent pacemaker implantation following temporary pacemaker implantation. A significant gender-based difference ($P < 0.05$) was observed only for the SSS indication, with the highest incidence in women (Table 2). Among the 183 patients, comorbidities were recorded with respective proportions as follows: cardiac-associated pathological factors, including DCM (7%), CAD (7%), TAVR (3%), and AMI (3%), and cardiac-associated risk factors, including HTN (13%), T2DM (11%), and HTN + T2DM (2%). All these variables exhibited no statistically significant differences ($P > 0.05$) between males and females (Table 2). Regarding treatment, both single- and dual-chamber procedures were performed among the study population, with 95% undergoing simpler CPs (173/183) [comprising 61.2% CPs with only ventricle paced, ventricle sensed, inhibited response, and rate modulation (VVIR) and 33.3% CPs with dual (atrium and ventricle) paced, dual sensed, dual response (triggered and inhibited) and rate modulation (DDDR)], 2% receiving ICDs (4/183), and 3% undergoing CRT (6/183). We found near-absolute use of simpler pacing for arrhythmia management, except for a small proportion receiving advanced pacing therapy.

Clinical presentation

Upon observation of the entire cohort, the adverse event rate was found to be 5.5% (10/183), with two adverse events recorded during telephonic follow-up. Gender-wise, the adverse event rate was 7.9% in females (6/76) and 3.7% in males (4/107). Eighty percent (8/10) of adverse events occurred in patients aged 50 years or older. Chi-square analysis was therefore performed between the incidence of events and age, and between the incidence of events and gender; however, no significant differences ($P > 0.05$) were observed in these analyses (Fig. 3).

All recorded events (n = 10) in the entire cohort (n = 183) were distributed as 3.8% device infections (7/183), 1.09% lead dislodgement (2/183), and 0.54% generator dysfunction (1/183). Chi-square statistics were applied to assess the association between event type and gender; however, no statistically significant differ-

Table 2. Indications and comorbidities data distributed by gender ($P < 0.05$)

	Women	Men	*P*-value
Indications			
CHB	37 (48.7%)	55 (51.4%)	0.552
AVB	19 (25%)	26 (24.3%)	0.498
SSS	23 (30.3%)	12 (11.2%)	< 0.05
TPI	4 (5.3%)	4 (3.7%)	0.467
LBBB	1 (1.3%)	4 (3.7%)	0.410
Co-morbidities			
HTN	8 (10.5%)	16 (14.9%)	0.645
T2DM	7 (9.2%)	13 (14.1%)	0.796
DCM	4 (5.3%)	9 (8.4%)	0.598
CAD	4 (5.3%)	8 (7.5%)	0.750
AMI	0 (0%)	6 (5.6%)	0.054
TAVR	1 (1.3%)	4 (3.7%)	0.410
HTN+T2DM	2 (2.6%)	1 (0.93%)	0.298

AMI, acute myocardial infarction; AVB, atrioventricular block; CAD, coronary artery disease; CHB, complete heart block; DCM, dilated cardiomyopathy; HTN, hypertension (systemic); LBBB, left bundle branch block; NSTEMI, non-ST-segment elevation MI; SSS, sick-sinus syndrome; T2DM, type-2 diabetes mellitus; TAVR, transcatheter aortic valve replacement; TPI, temporary pacemaker implantation.

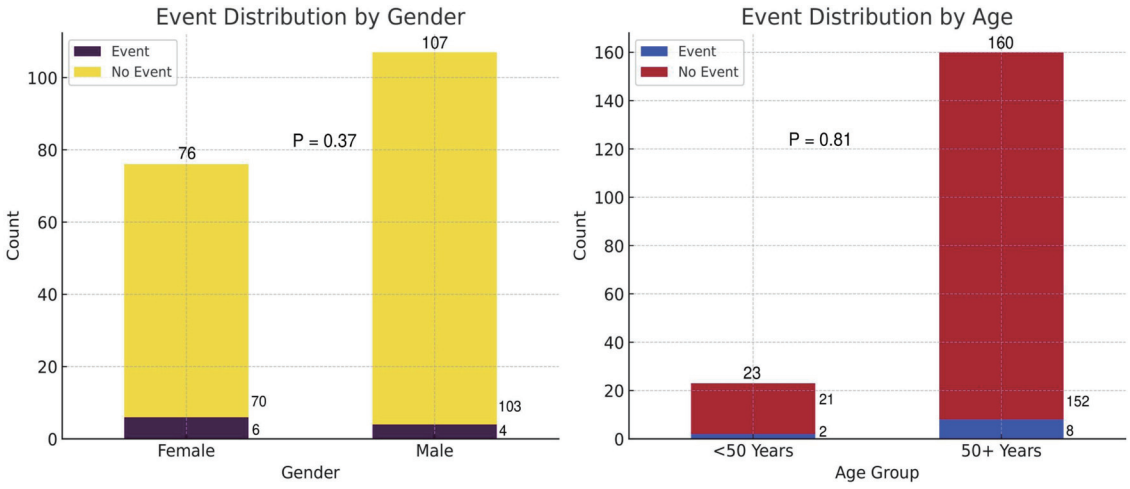


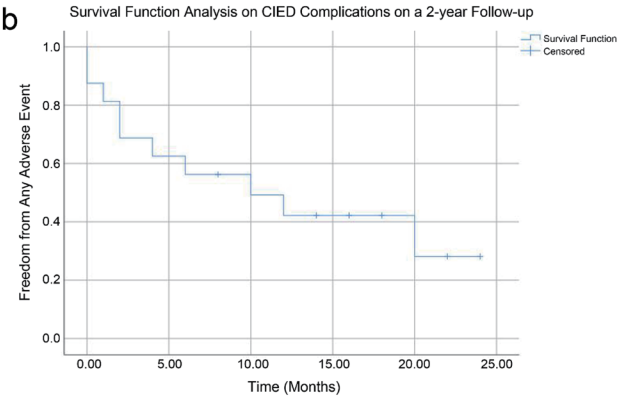
Fig. 3. A representation of the number of adverse events distributed by gender and age. This estimation compares the number of events found in males versus females and shows the event count in two age groups: adverse events in the population aged<50 years and ≥50 years.

ence ($P > 0.05$) was observed for the analyzed variables (Fig. 4a). The survival curve free from any adverse events showed a notable decline during the first six months, followed by a gradual stabilization, highlighting the success of pacemaker implantation after half a year (Fig. 4b). Patient-related predictors or covariates, such as age, treatments, indications, and comorbidities, for the incidence of adverse events within the two-year follow-up period are shown in Figure 4c, indicating no significant independent impact on the occurrence of adverse events ($P > 0.05$), which was further supported by the Kaplan–Meier survival curves stratified by covariates (Fig. 4d). Furthermore, Cox proportional hazards regression analysis also showed no statistically significant effect ($P = 0.098$)

a

Complications	Women	Men	P-value
Total Adverse Events	6 (7.9%)	4 (3.7%)	
Device Infections	5 (6.6%)	2 (1.8%)	0.67
Lead Dislodgement	0 (0%)	2 (1.8%)	0.25
Generator Dysfunction	1 (1.3%)	0 (0%)	1.00

b



c

Patient Characteristics	HR	95% CI	P-value
Age	1.02	0.692 – 1.102	0.40
Treatments	0.08	0.003 – 2.141	0.13
Indications	0.12	0.011 – 1.354	0.08
Co-morbidities	0.21	0.025 – 1.777	0.15

d

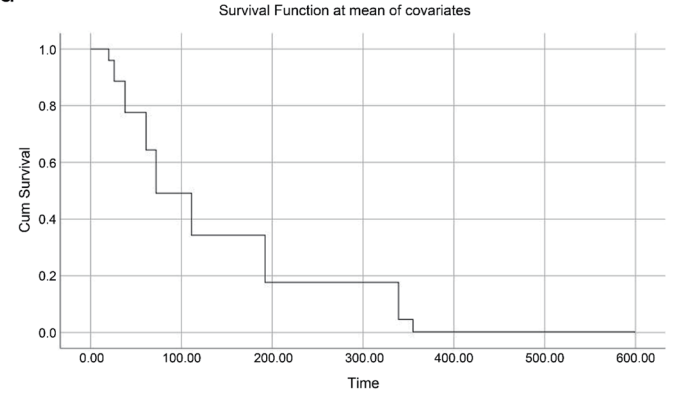


Fig. 4. A representation of the types of adverse events distributed by gender, survival free from any adverse events, and the effect of covariates on the occurrence of adverse events. a: Comparison of the incidence of adverse events between males and females. b: Survival analysis presenting freedom from any adverse events. c & d: Analysis of the impact of multiple covariates on the occurrence of adverse events using the Cox proportional hazards regression model.

Table 3. ADRMS-submitted reports and their safety identification numbers

Serial No.	Reporting date	Adverse events reporting	Gender	Worldwide unique ID
1	26-06-2023	Generator dysfunction	F	IN-IPC-MD10521
2	13-07-2023	Device infection	F	IN-IPC-MD10566
3	14-07-2023	Lead dislodgement	M	IN-IPC-MD10574
4	24-07-2023	Device infection	F	IN-IPC-MD10712
5	16-12-2023	Device infection	M	IN-IPC-MD13487
6	15-01-2024	Device infection	F	IN-IPC-MD13745
7	20-11-2024	Device infection	F	IN-IPC-MD21112
8	20-01-2025	Device infection	M	IN-IPC-MD21885
9	14-07-2023	Lead dislodgement	M	Recorded on telephonic follow-up
10	21-01-2024	Device infection	F	Recorded on telephonic follow-up

ADRMS, adverse drug reaction monitoring system.

of baseline covariates on the incidence of adverse events at the two-year follow-up. Only three fatalities (3/10) were observed during the study; therefore, no separate survival analysis for mortality was performed. These deaths were considered adverse events and were included in the total number of adverse events (n = 10).

Adverse event reporting

An automatic worldwide unique ID was generated by the ADRMS upon reporting an ICSR (Table 3). Adverse events identified during telephonic follow-up were not reported due to MvPI timeline constraints; therefore, no ID was generated for these cases. However, telephonic cases were included for estimating the overall adverse event rate (5.5%), which was found to be comparable with previous reports.[19–21]

Discussion

The results of this study provide valuable insights into the demographics, clinical characteristics, and outcomes of patients undergoing pacemaker and related device implantation at a tertiary care hospital. Our findings reinforce the understanding of patient profiles and the associated risks of these devices. Previous studies indicate that the prevalence of pacemaker implantation increases significantly with age, particularly among those aged 85–94 years.[23,24] Moreover, the age of 65 years or older has been observed as the age at which people are more likely to undergo pacemaker implantation.[5–7] In our study, the average age of 63 years for pacemaker implantation was also found to be close to these reports. Therefore, this age level reflects a typical demographic parameter for these types of cardiac interventions.[3,11]

Pacemaker implantation can occur due to various arrhythmic reasons; however, in most cases, AVB, CHB, and SSS are considered the primary indications for pacemaker implantation. In our observations, the primary indication for pacemaker implantation was CHB. These findings are consistent with existing literature,[25] which often cites CHB as a leading reason for pacemaker placement.

Our study's comprehensive assessment of comorbidities is particularly noteworthy. These comorbidities are well documented in previous literature as significant factors that can influence both device selection and procedural outcomes. For instance, patients with multiple comorbidities face a higher risk of morbidity and mortality during and after pacemaker implantation.[26–28] Previous studies also show that cardiac-associated comorbidities such as DCM and CAD are predisposing factors that support arrhythmia induction. In our study, we also observed an equal incidence of DCM and CAD among patients undergoing pacemaker implantation, particularly in advanced pacing systems such as CRT.[29,30] In addition, cardiac-associated risk factors such as HTN and T2DM are known primary risk factors for complex heart diseases that lead to abnormal rhythm complications. Similar findings were recorded in our study, suggesting that comorbidities such as HTN and T2DM could increase the rate of pacemaker implantation.

The distribution of pacemaker types—approximately 61% VVIR, 33% DDDR, and a smaller percentage for ICD and CRT devices (6%)—highlights a preference for simpler pacing strategies in this cohort. This also aligns with trends in clinical practice, where VVIR and DDDR devices are favored for their effectiveness in managing bradyarrhythmias. In support of these findings, a previous study compared simpler and advanced pacing systems and reported that DDDR pacemakers are increasingly used, particularly in older populations,[31] due to their ability to provide more physiological pacing. In our study, we found that single-chamber pacemaker implantation (VVIR) was more likely associated with less complex cardiac conditions, such as AVB and SSS, whereas dual-chamber implantation (DDDR) was more often associated with advanced cardiac complications, such as CHB and left bundle branch block with severe systemic left ventricular dysfunction. These results are supported by existing literature.[32,33]

Overall, there were no statistically significant gender-wise differences in age distribution at first-time pacemaker implantation, indication distribution, comorbidity status (except for SSS, $P < 0.05$), or type of device implanted. These findings strongly indicate that females are equally likely as males to receive pacemaker implantation with respect to age, indications, comorbidity status, and treatment type. However, a higher incidence of adverse events in females (7.9%) compared to males (3.7%) was observed, raising concerns about potential gender differences in response to cardiac interventions[22]; nevertheless, this difference did not reach statistical significance. This observation may suggest that other factors, such as physiological variations, procedural complexity, or postoperative care, could contribute to this difference.

Age-related analysis revealed that the majority of adverse events (80%) occurred in patients aged 50 years or older.[34] This finding aligns with existing literature suggesting increased suscep-

tibility to procedural complications and infections in older individuals due to age-related physiological changes, comorbidities, or prolonged healing times.[34] However, statistical analysis did not confirm a significant association between age and adverse events ($P > 0.05$), implying that age alone may not be a definitive predictor of adverse events.

Among the types of adverse events observed, device infection emerged as the most prevalent complication (70%), affecting 3.8% of the total cohort. This finding aligns with previous reports identifying device infection (approximately 1.5%) as a major contributor to the overall incidence of CP-associated adverse events.[35] In our study, of the total 5.5% incidence of adverse events, device infections accounted for the majority (3.8%). In contrast, lead dislodgement and generator dysfunction were less frequent, consistent with earlier studies reporting infections as one of the leading complications following pacemaker and related device implantation.[36–38] Chi-square analysis did not indicate a significant association between event type and gender, suggesting that the distribution of adverse event types is not strongly influenced by gender-based physiological differences.

Kaplan–Meier survival analysis demonstrated a marked decline in survival free from adverse events during the initial six months post-implantation, followed by gradual stabilization. This trend highlights the critical importance of early postoperative monitoring and infection prevention strategies, as most complications appear to occur within the first six months following device implantation. The stabilization of the survival curve beyond six months suggests that the risk of adverse events decreases over time, reinforcing the long-term safety of pacemaker devices once the initial postoperative period has passed. Furthermore, Cox proportional hazards regression analysis did not identify a statistically significant predictive impact of baseline covariates such as age, treatment indications, or comorbidities on adverse event occurrence over a two-year follow-up period ($P = 0.098$). This suggests that adverse events may be influenced by multifactorial elements rather than a single identifiable risk factor, including age, gender, or comorbidity status.

The mortality rate of 1.6% (3/183) observed in this study was relatively low at our hospital; therefore, a separate survival analysis for mortality was not performed. However, it is important to acknowledge that this study involved a relatively short follow-up period and included a small proportion of advanced pacing procedures. Consequently, long-term prospective studies would be advantageous to more precisely define the safety profile and other clinical outcomes of these devices.

The MvPI aims to build a strong and reliable system for monitoring the safety and performance of medical devices such as cardiovascular implants. Its primary goal is to identify, assess, and prevent adverse events or device failures to protect patient health. Managed by the IPC, the MvPI encourages healthcare professionals and users to report device-related problems. It also works to align India's medical device monitoring system with international standards, such as those of the World Health Organization, for medical device practices in healthcare,[17,39] thereby supporting global efforts in materiovigilance through transparent reporting and evidence-based safety improvements. In this study, the proactive reporting of adverse events through the ADRMS to the IPC under the MvPI demonstrates a commitment to patient safety and regulatory compliance at our hospital. This approach aligns with global best practices in pharmacovigilance and materiovigilance. Effective adverse event reporting systems are therefore crucial for ensuring safety and mitigating risks associated with medical devices,[40] enabling prompt documentation and response to complications.

We would like to define the strengths of our study in-terms of three key characteristics. *Methodological rigor*: the prospective study design, ethical approval (IECJNMC/1662), and use of SPSS for statistical analyses (Mann–Whitney, chi-square, Cox regression) align with standards for robust methodology. *Novel contribution:* real-time reporting of adverse events to the MvPI and the establishment of gender-based comparisons address gaps in Indian CIED literature. *Clinical relevance:* the observed 5.5% adverse event rate, higher incidence within the first six months, and alignment with global data (1.5–4% complication rates) provide actionable insights. Conversely, this study has certain limitations. Conducted at a single medical facility, it provides valuable insights but may not fully represent the broader spectrum of adverse events due to the short study duration. While the study sheds light on potential causes of adverse events, the small number observed may limit generalizability, and these findings may be influenced by the limited follow-up period. Additionally, reliance on telephonic follow-up may hinder specific inferences. Other limitations include small sample sizes in the CRT and ICD groups, inherent differences among device groups, and lack of randomization, which may affect overall inferences and reduce the strength of comparisons. The small proportion of advanced pacing therapies in the cohort may also influence gender-based analyses of these treatments. Finally, the relatively small sample size and short duration of patient monitoring may limit the ability to draw definitive conclusions regarding mortality, actuarial survival, and long-term outcomes.

Future directions

This study emphasizes the need for further research to improve post-implantation outcomes of CIEDs in low- or middle-income countries. Future investigations should aim to include larger sample sizes and longer follow-up periods to achieve better outcomes. A multicenter, prospective or retrospective study design would strengthen the results and yield more reliable insights into trends in serious adverse events and mortality, particularly among high-risk groups such as elderly patients. In addition, researchers should examine the influence of socioeconomic factors on postoperative outcomes, such as access to antimicrobial therapies. Incorporating the reporting of adverse events into a national medical device safety initiative into future studies will also provide a more comprehensive understanding of the safety and long-term impact of such cardiac implants.

Addressing these research gaps will not only refine the clinical practice of CPs and related implants but also guide policy decisions to strengthen cardiac care in resource-limited settings.

Conclusions

Our study supports the overall safety of CIED implantation, with a fairly low incidence of adverse events and mortality. The observed adverse event rate of 5.5% is close to both international and Indian data. Our findings also indicate that the majority of adverse events occurred in patients aged over 50 years. Hence, age may be a concerning factor in the implantation of such devices; however, this was not statistically significant in our results. Gender-based examination showed no disparities between males and females across the various evaluated variables. Our findings emphasize the importance of early postoperative monitoring and prevention of complications such as device infection and lead dislodgement; however, the smaller sample size and short follow-up duration

warrant further investigation to obtain more specific outcomes. Our study also supports the vision of the MvPI and may be helpful in conducting similar single-arm, single-center observational studies on the safety and reporting of CPs in larger cohorts with extended follow-up.

Study concept and design (JA, AH, SZR), acquisition of data, analysis and interpretation of data, drafting of the manuscript (JA), critical revision of the manuscript for important intellectual content (SZR, AH, MAH, MS), final review and editing (MAH, MS), and study supervision (SZR, AH). All authors have made significant contributions to this study and have approved the final manuscript.

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Conflict of interest

The authors declare no conflicts of interest.

Ethical statement

Ethical approval for this study was obtained from the Institutional Ethics Committee of J.N. Medical College & Hospital (Aligarh Muslim University, Aligarh, India) under approval number IECJNMC/1662. Permission to access and analyze the data collected from the Catheterization Laboratory was granted by the Department of Cardiology (J.N. Medical College & Hospital). Individual informed consent was obtained from each patient prior to his/her participation in the study. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki (as revised in 2024).

Data sharing statement

No additional data are available.

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